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(54) Title: COMPOSITION FOR ORAL CONSUMABLE FILM

(57) Abstract: Disclosed is an orally consumable film composition including starch and alginate at a ratio of 1:2.5 to 1:4. The composition further includes antimicrobial agents, flavoring agents, fillers, plasticizing agents, stabilizing agents, saliva secretion-stimulating agents, sweetening agents, pharmaceutically active agents, and the like.

COMPOSITION FOR ORAL CONSUMABLE FILM

Technical Field

The present invention relates to an orally consumable film composition containing starch and alginate at a ratio of 1:2.5 to 1:4. A film prepared using such a composition has excellent tensile strength and elongation and is useful in the delivery of various pharmaceutically active agents.

Background Art

Various oral cleaning products such as toothpastes and gargles have limitations in time and place upon use. Also, gums and lozenges are not always socially acceptable everywhere. A mouthspray that is a portable oral cleansing product typically generates a noise, and attracts public attention when used in public places.

To meet the requirements of consumers to clean their mouths simply and without time and place limitations, edible films were developed using various biopolymers.

A representative example of the biopolymers used in preparation of the edible films is pullulan, and use of the pullulan is described in a plurality of literatures. For example, U.S. Pat. No. 6,596,298 discloses a film including pullulan and antimicrobially effective amounts of thymol,

methylsalicylate, eucalyptol and menthol. Also, many research publications disclose films prepared using pullulan as a film-forming agent and including various pharmaceutical agents. However, pullulan is expensive, and its domestic supply depends on imports. Therefore, there is a need for the development of alternative film-forming agents.

In this regard, orally consumable films were prepared using starch instead of pullulan. However, such films are fragile, and thus, inconvenient in handling and storage. Employment of a modified starch was suggested to address these problems. Also, efforts were made to replace pullulan with cellulose. However, such alternatives lack beneficial film properties of pullulan, such as rapid dissolvability, high oral cleaning effect and easy film preparation.

Disclosure of the Invention

The present inventors found that a mixture of starch and alginate in a predetermined ratio has physical properties, in particular, tensile strength and elongation, suitable as a film-forming agent to produce orally consumable film, is not self-adhering, dissolves rapidly upon oral application and can contain relatively higher amounts of oral care agents such as antimicrobial/flavoring agents, resulting in an excellent oral cleaning effect. Based on this finding, the present inventors completed this

invention.

Best Mode for Carrying Out the Invention

The present invention relates to an orally consumable film composition, which is characterized by comprising a mixture of starch and alginate at a ratio of 1:2.5 to 1:4.0.

The conventional film-forming agents include pullulan, alginate, starch, gelatin, and diverse gums, for example, carageenan, xanthan gum, locust bean gum (LBG) and gellan gum. These biopolymers are dissolved in water in predetermined amounts, casted and then dried to form films.

The above film-forming agents have superior physical properties when used in combination compared to being used individually. The present inventors found that, when used as a film-forming agent, a mixture of starch and alginate at a ratio of 1:2.5 to 1:4.0 has excellent physical properties, in particular, tensile strength and elongation, and is capable of containing high amounts of various oral care agents, such as antimicrobial agents, flavoring agents and oral malodor-removing agents. Thus, the mixture of starch and alginate is suitable for preparation of orally consumable films for oral cleaning.

The starch used to produce the film composition of the present invention includes all starch derived from

naturally occurring sources. Also suitable are starches derived from a plant obtained by various breeding techniques including cross-breeding, translocation, inversion and transformation. Typical sources for the starches are cereals, tubers, roots, legumes and fruits, which comprise corn, potato, sweet potato, banana, barley, wheat, rice, sago, amaranth, tapioca, arrowroot, canna and sorghum. The starch used in the film composition may be modified to meet desired film properties, as follows: the film should have sufficient tensile strength and elongation and be not deformed upon film formation, should be moisture-resistant to prevent self-adhering, and should be rapidly dissolved in an aqueous solution. To achieve these film properties, the starch may be modified by methods known in the art, such as physical, chemical and enzymatic modifications.

Examples of physically modified starches include sheared starches or thermally inhibited starches. Examples of chemically modified starches include cross-linked derivatives, acetylated derivatives, organically esterified derivatives, hydroxyethylated derivatives, hydroxypropylated derivatives, phosphorylated derivatives, inorganically esterified derivatives, cationic derivatives, anionic derivatives, zwitterionic derivatives, succinate derivatives and substituted succinate derivatives. Such modifications are well known in the art. In detail, Perfectamyl AC esterified potato starch, Kreation MB modified tapioca starch

and Perfectamyl HT2X modified tapioca starch are known.

In particular, suitable are hydroxyalkylated starches, such as hydroxypropylated starches or hydroxyethylated starches, and succinated starches, such as octenylsuccinated starches or dodecylsuccinated starches. Of them, the hydroxyalkylated starches are more beneficial in order to offer better elongation to films prepared by using the same.

To remove the odor/color innately present in the polysaccharides or generated, the starches having properties suitable in the practice of the present invention may be purified during the processing by a method known in the art.

The alginate used at a mixed state with the starch may be derived from diverse sources, for example, brown algae or microorganisms, and used as a gel-forming agent, a coagulating agent and a dietary fiber due to its very strong affinity to divalent metals. In detail, the alginate is used as a stabilizing agent of highly viscous foods, such as ice creams, sorbets, syrups and sweet red-bean soup, as well as in the preparation of adhesives, lubricants, films, fibers, and the like. Typically, the alginate is used in the form of sodium alginate, for example, Manucol LB.

When the ratio of the starch to the alginate is less than 1:2.5 or exceeds 1:4.0, their film-forming ability was

deteriorated. In detail, in case of using the alginate alone as a film-forming agent (Comparative Example 2), the resulting film had a high tensile strength but a low elongation. Thus, the film was easily deformed when containing flavors and oils. Also, since the unique smell of the alginate halves flavors, a favoring agent should be used in higher amounts. This higher-content flavoring agent makes for the film be easily deformed. In case of using the starch alone as a film-forming agent (Comparative Example 1), the resulting film had good elongation, but had low strength and was poorly detachable from application regions and hard to handle. In the combinational use of the starch and the alginate, when the content of the starch increased, the resulting film was similar to that prepared using the starch alone. In contrast, when the content of the alginate increased, for example, to four times, the resulting film had high tensile strength but low elongation, and was reduced in the content of flavors and oils and easily deformed. When the ratio of the starch to the alginate ranged from 1:2.5 to 1:4, the resulting film was excellent in both tensile strength and elongation, and had increased contents of pharmaceutically active agents such as flavoring agents and antimicrobial agents.

Preferably, the ratio of the starch to the alginate, used as a film-forming agent contained in the orally consumable film composition of the present invention,

ranges from 1:3.0 to 1:3.5. A film prepared using such a composition of the present invention has physical properties suitable for use as an orally consumable film, in particular, a good tensile strength (higher than 20 Mpa, preferably, higher than 25 Mpa), a good elongation (higner than 3%, preferably, higher than 5%) and a high solubility (dissolved within several seconds).

To gain physical properties suitable for use as an orally consumable film, in addition to the aforementioned film-forming agents in the predetermined ratio, any suitable plasticizing agents or softners may be added to the film composition of the present invention. Examples of the plasticizing agents include polyols, which are exemplified by ethylene glycol, propylene glycol, sugar alcohols (e.g., sorbitol, mannitol, maltitol, lacticol, xylitol, etc.) and mono-, di- and oligo-saccharides (e.g., fructose, glucose, sucrose, maltose, lactose and high fructose corn syrup and ascorbic acid), polycarboxylic acids, which are exemplified by citric acid, maleic acid, succinic acid, polyacrylic acid and polymaleic acid), and polesters, which are exemplified by glycerin, triacetate, acetylated monoglyceride, diethyl phthalate, triethyl citrate, tributyl citrate, acetyl triethyl citrate and acetyl tributyl citrate). These plasticizing agents increase elongation and solubility but reduce tensile strength. It is more preferable that such softners are used

in combination than individually. Preferably, sorbitol, glycerine, propylene glycol, etc. are used together. The content of the plasticizing agents is about 0 to 20% by weight and preferably, about 1 to 5% by weight, based on the total weight of the film composition. The sorbitol contained in the film composition may increase the moisture content in films.

As used herein, the term "the total weight of the film composition" is intended to indicate the total weight of substances used in the orally consumable film of the present invention.

In order to increase tensile strength of the orally consumable film, in addition to the above film-forming agents, other high molecular weight biopolymers as stabilizing agents may be added to the film composition. Examples of the biopolymers include carageenan, LBG (locust bean gum), xanthan gum and gellan. These biopolymers increase viscosity of the film composition and tensile strength. Due to such properties, when a film containing high-content flavors and oils is intended to be prepared, the biopolymers are capable of preventing the film from being easily deformed. The content of the biopolymers is about 0 to 5% by weight, and preferably, about 0.5 to 2% by weight, based on the total weight of the film composition.

Molecular weights of the high molecular weight film-forming agents are important in the film formation.

Preferable are film-forming agents having a molecular weight ranging from 150 kDa (kilodaltons) to 300 kDa. When having a molecular weight exceeding the range, the film-forming agents have remarkably deteriorated physical properties. In contrast, when the film-forming agents have a molecular weight less than the range, the resulting film is easily deformed and more difficult to handle upon maturation, slitting and cutting during its processing.

Any suitable food-grade bulk filler may be added to the present composition. This can reduce any slimy texture as well as provide structure to the film. Examples of the filler include microcrystalline cellulose, cellulose polymers, magnesium carbonate, calcium carbonate, ground limestone, silicates, clay, talc, titanium dioxide, mono-calcium phosphate, di-calcium phosphate and tri-calcium phosphate. In order to reduce viscosity and improve solubility by evenly dispersing a plurality of film-forming agents, the microcrystalline cellulose is preferable, which is exemplified by Avicel. The content of the filler is about 0 to 5% by weight, and preferably, about 0.1 to 1% by weight, based on the total weight of the film composition.

In case of being used for oral cleaning, the present composition may further include antimicrobial/flavoring agents. The flavoring agents that can be used include those known to the skilled artisan, such as natural and artificial flavors. These flavoring agents may be chosen from synthetic

flavor oils and flavoring aromatics, and/or oils, oleo resins and extracts derived from plants, leaves, flowers, fruits and the like, and combinations thereof. Representative flavor oils include spearmint oil, cinnamon oil, peppermint oil, clove oil, bay oil, thyme oil, cedar leaf oil, oil of nutmeg, oil of sage, and oil of bitter almonds. Also useful are artificial, natural or synthetic fruit flavors such as vanilla, chocolate, coffee, cocoa and citrus oil, including lemon, orange, grape, lime and grapefruit; and fruit essences including apple, pear, peach, strawberry, raspberry, cherry, plum, pineapple, apricot and the like. These flavoring agents may be used individually or in admixture. Commonly used flavoring agents include mints such as peppermint, artificial vanilla, cinnamon derivatives, and various fruit flavors, whether employed individually or in admixture. Flavoring agents such as aldehydes and esters including cinnamyl acetate, cinnamaldehyde, citral, diethylacetal, dihydrocarvyl acetate, eugenyl formate, p-methylanisole, and the like may also be used. Generally, any flavoring agent or food additive, such as those described in Chemicals Used in Food Processing, publication 1274 by the National Academy of Sciences, pages 63-258, may be used. Further examples of aldehyde flavoring agents include, but are not limited to acetaldehyde (apple); benzaldehyde (cherry, almond); cinnamic aldehyde (cinnamon); citral, i.e., alpha citral (lemon, lime); neral, i.e. beta citral (lemon, lime); decanal

(orange, lemon); ethyl vanillin (vanilla, cream); heliotropine, i.e., piperonal (vanilla, cream); vanillin (vanilla, cream); alpha-amyl cinnamaldehyde (spicy fruity flavors); butyraldehyde (butter, cheese); valeraldehyde (butter, cheese); citronellal (modifies, many types); decanal (citrus fruits); aldehyde C-8 (citrus fruits); aldehyde C-9 (citrus fruits); aldehyde C-12 (citrus fruits); 2-ethyl butyraldehyde (berry fruits); hexenal, i.e. trans-2 (berry fruits); tolyl aldehyde (cherry, almond); veratraldehyde (vanilla); 2,6-dimethyl-5-heptenal, i.e. melonal (melon); 2-6-dimethyloctanal (green fruit); and 2-dodecenal (citrus, mandarin); cherry; grape; mixtures thereof; and the like.

The flavoring agent is an oil type including a water-soluble powder type. Among the oil-type flavoring agents, menthol, peppermint and methylsalicylate have antimicrobial efficacy. In case that such an antimicrobial, oil-type flavoring agent is employed, an emulsifying agent may be added to the film composition to allow for the blending of the flavoring agent with water. The amount of flavoring agent employed may vary depending on a plurality of factors such as flavor type, individual flavor and strength desired. Such variations are within the capabilities of those skilled in the art without the need for undue experimentation. Typically, the content of the flavoring agent is about 0.1 to 20% by weight, and preferably, about 1 to 5% by weight, based on the total weight of the film composition.

In particular, since the flavoring agent having antimicrobial efficacy, such as menthol, peppermint or methylsalicylate, is in an oil form, it is used along with an emulsifying agent to allow for the blending with water-soluble substances. Examples of the emulsifying agent include glycerin fatty acid esters, sucrose fatty acid esters and lecithin. In particular, the highly hydrophilic sucrose fatty acid ester, sucrose fatty acid ester S-1670 may be used in an amount of about 0 to 5% by weight, and preferably, about 0.1 to 2.0% by weight, based on the total weight of the film composition.

In addition to the above antimicrobial agent, the present composition may include sulfur-precipitating agents to reduce oral malodor. These agents bind with, and inactivate, the volatile sulfur compounds causing oral malodor. Sulfur precipitating agents useful in the present invention include metal salts such as copper salts and zinc salts. Preferred salts include copper gluconate, zinc citrate and zinc gluconate.

In addition, the present composition may further include sweeteners. Examples of suitable sweeteners include water-soluble sweetening agents such as monosaccharides, disaccharides and polysaccharides such as xylose, ribose, glucose, mannose, galactose, fructose, sucrose, maltose, invert sugar, partially hydrolyzed starch, corn syrup solids, dihydrochalcones, monellin and steviosides; water-soluble

artificial sweeteners such as the soluble saccharin salts, i.e., sodium or calcium saccharin salts, cyclamate salts, the sodium, ammonium or calcium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazine-4-one-2,2-dioxide, the potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazine-4-one-2,2-dioxide (acesulfame-K), the free acid form of saccharin, and the like; dipeptide-based sweetening agents, such as L-aspartic acid derived sweeteners, such as L-aspartyl-L-phenylalanine methyl ester (aspartame), L-alpha-aspartyl-N-(2,2,4,4-tetramethyl-3-thietanyl)-D-alaninamide hydrate, methyl esters of L-aspartyl-L-phenylglycerin and L-aspartyl-L-2,5, dihydrophenyl-glycine, L-aspartyl-2,5-dihydro-L-phenylalanine, L-aspartyl-L-(1-cyclohexyen)-alanine, and the like; water-soluble sweetening agents derived from naturally occurring water-soluble sweetening agents, such as a chlorinated derivative of ordinary sugar (sucrose), for example, sucralose; and protein-based sweetening agents such as thaumatoccous danielli. Typically, highly sweet synthetic sweetening agents rather than natural one are used, and sucralose, acesulfame-K, aspartame and steviosides are frequently used. Preferably, sucralose, acesulfame-K and aspartame are used in an admixture. The content of the sweetening agents is about 0.01% to 2.0% by weight, and preferably, about 0.2% to 1.0% by weight, based on the total weight of the film composition.

In addition, the present composition may further

include acidifiers. The acidifiers stimulate saliva secretion, affect taste of films prepared using the present composition, and attribute to improvement of gel strength. Examples of the acidifiers include various acids, such as citric acid, lactic acid, malic acid, succinic acid, ascorbic acid, adipic acid, fumaric acid and tartaric acid. Preferable are citric acid and malic acid. The content of the acidifiers is about 0 to 2.0% by weight, and preferably, about 0.1 to 1.0% by weight, based on the total weight of the film composition.

In addition, the present composition may further include coloring agents. The coloring agents are used in amounts effective to produce a desired color. Examples of the coloring agents include colors of natural foods and edible dyes. Such coloring agents are typically known as FD&D dyes.

In addition to the aforementioned additives, the present composition may include stabilizing agents, emulsifying agents, cooling agents and various therapeutic agents for medical use including vitamins. The therapeutic agents can achieve multiple effects when used in combination with the above antimicrobial agents for oral cleaning.

The present composition may further include pharmaceutical active agents. The term "pharmaceutically active agents", as used herein, is intended to indicate

agents other than foods, which promote a structural and/or functional change in and/or on bodies to which they have been administered. These agents should be physiologically acceptable and compatible with the film. Suitable pharmaceutically active agents include, but are not limited to antimicrobial agents, such as triclosan, cetyl pyridium chloride, domiphen bromide, quaternary ammonium salts, zinc compounds, sanguinarine, fluorides, alexidine, octonidine, EDTA, and the like; non-steroidal anti-inflammatory drugs, such as aspirin, acetaminophen, ibuprofen, ketoprofen, diflunisal, fenoprofen calcium, naproxen, tolmetin sodium, indomethacin, and the like; anti-tussives, such as benzonatate, caramiphen edisylate, menthol, dextromethorphan hydrobromide, chlophedianol hydrochloride, and the like; decongestants, such as pseudoephedrine hydrochloride, phenylepherine, phenylpropanolamine, pseudoephedrine sulfate, and the like; anti-histamines, such as brompheniramine maleate, chlorpheniramine maleate, carbinoxamine maleate, clemastine fumarate, dexchlorpheniramine maleate, diphenhydramine hydrochloride, diphenylpyraline hydrochloride, azatadine meleate, diphenhydramine citrate, doxylamine succinate, promethazine hydrochloride, pyrilamine maleate, tripelennamine citrate, triprolidine hydrochloride, acrivastine, loratadine, brompheniramine, dexbrompheniramine, and the like; expectorants, such as guaifenesin, ipecac, potassium iodide, terpin hydrate, and the like; anti-

diarrheals, such a loperamide, and the like; H2-antagonists, such as famotidine, ranitidine, and the like; proton pump inhibitors, such as omeprazole, lansoprazole, and the like; general nonselective CNS depressants, such as aliphatic alcohols, barbiturates and the like; general nonselective CNS stimulants such as caffeine, nicotine, strychnine, picrotoxin, pentylenetetrazol and the like; drugs that selectively modify CNS function such as phenyhydantoin, phenobarbital, primidone, carbamazepine, ethosuximide, methsuximide, phensuximide, trimethadione, diazepam, benzodiazepines, phenacemide, pheneturide, acetazolamide, sulthiame, bromide, and the like; antiparkinsonism drugs such as levodopa, amantadine and the like; narcotic-analgesics such as morphine, heroin, hydromorphone, metopon, oxymorphone, levorphanol, codeine, hydrocodone, xycodone, nalorphine, naloxone, naltrexone and the like; analgesic-antipyretics such as salycilates, phenylbutazone, indomethacin, phenacetin and the like; and psychopharmacological drugs such as chlorpromazine, methotrimeprazine, haloperidol, clozapine, reserpine, imipramine, tranylcypromine, phenelzine, lithium and the like.

Preferred pharmaceutically active agents includes chlorpheniramine maleate, brompheniramine maleate, dexchlorpheniramine, triprolidine hydrochloride, acrivastine, azatadine maleate, loratidine, phenylephrine hydrochloride,

dextromethorphan hydrochloride, ketoprofen, sumatriptan succinate, zolmitriptan, loperamide, famotidine, nicotine, caffeine, diphenhydramine hydrochloride, and pseudoephedrine hydrochloride, and their amounts per strip are well known in the art.

The film composition containing pharmaceutically active agents may also include a triglyceride. Examples of the triglyceride include vegetable oils such as corn oil, sunflower oil, peanut oil, olive oil, canola oil, soybean oil and mixtures thereof. The film composition containing pharmaceutically active agents may also include a preservative, such as sodium benzoate and potassium sorbate; a polyethylene oxide compound; and propylene glycol. The pharmaceutically active agent used in the film may be coated to mask the taste of the active ingredient and to gain other additional effects.

A film prepared using the present composition having the above composition has a tensile strength of 20 Mpa or more, and preferably 25 Mpa or more, and an elongation of 3% or more, and preferably 5% or more. Due to these properties, the film is easy to handle during and after processing, and can contain antimicrobial/flavoring agents in higher contents. Thus, the film is effective in oral cleaning and delivery of additional medicients.

The present invention will be explained in more detail

with reference to the following examples. However, the following examples are provided only to illustrate the present invention, and the present invention is not limited to them.

EXAMPLE 1

0.144 g of Avicel was added to 71.891 g of water in a container at room temperature, and homogeneously mixed for 20 min. 0.479 g of sucrose fatty acid ester S-1670 was added to the above solution and mixed for 20 min. Subsequently, 1.198 g of sorbitol, 1.198 g of glycerin and 0.240 g of propylene glycol were added to the solution, and heated to 80°C. When the temperature reached 80°C, the heating was stopped, and 14.378 g of alginate (manucol LB), 0.288 g of carageenan, 0.192 g of LBG and 0.144 g of xanthan gum were added to the resulting solution, followed by mixing for one hour. Then, 4.793 g of HP-starch dissolved in cool water was added to the above-obtained solution, followed by mixing for one hour. After mixing was completed, the temperature was lowered to 50°C, and 0.096 g of citric acid, 0.144 g of malic acid, 0.479 g of sucralose, 1.246 g of menthol, 0.479 g of herb cotton flavor, 1.150 g of peppermint oil, 0.958 g of citrus oil, 0.479 g of spearmint powder, 0.014 g of methylsalicylate and 0.010 g of a pigment were sequentially added to the above-obtained solution. After mixing was completed, the

resulting solution was filtered, transferred to a storage tank and defoamed overnight, and agitated for 30 min with a low speed before being coated. The obtained admixture was coated using a coating device, air-dried, and slitted with a desired size. The slitted samples were maturated for three to seven days. After the maturation was completed, the samples were cut with a desired size, thus yielding films.

Tensile strength (TS) and elongation (E) of the films were measured according to the standard ASTM test procedure D 882-88 using a texture analyzer (TX-HD, Stable Micro Systems, UK) in an incubator. Before testing, the films were equilibrated in water contents by being incubated in an incubator at 25°C under a relative humidity of 50% for 48 hrs. The films were cut with a size of 2.54cm(W)× 10cm(L), and the test was carried out with a crosshead speed of 500 mm/min and a grip separation of 50 mm. The test was repeated nine times, and mean and SD values were calculated. The measured tensile strength values were expressed as Mpa, while the measured elongation values were expressed as %.

As a result, the films were found to have a tensile strength of 28.230 Mpa and an elongation of 7.767%.

COMPARATIVE EXAMPLE 1

0.221 g of Avicel was added to 73.765 g of water in a container at room temperature, and homogeneously mixed for 20

min. 0.738 g of sucrose fatty acid ester S-1670 was added to the above solution and mixed for 20 min. Subsequently, 1.844 g of sorbitol, 1.844 g of glycerin and 0.369 g of propylene glycol were added to the solution, and heated to 80°C. When the temperature reached 80°C, the heating was stopped, 0.443 g of carageenan, 0.295 g of LBG and 0.221 g of xanthan gum were added to the resulting solution, followed by mixing for one hour. Then, 13.278 g of HP-starch dissolved in cool water was added to the above-obtained solution, followed by mixing for one hour. After mixing was completed, the temperature was lowered to 50°C, and 0.148 g of citric acid, 0.221 g of malic acid, 0.058 g of sucralose, 0.058 g of acesulfame-K, 0.116 g of aspartame, 1.770 g of menthol, 0.738 g of herb cotton flavor, 1.623 g of peppermint oil, 1.475 g of citrus oil, 0.738 g of spearmint powder, 0.022 g of methylsalicylate and 0.015 g of a pigment were sequentially added to the above-obtained solution. After mixing was completed, the resulting solution was filtered, transferred to a storage tank and defoamed overnight, and agitated for 30 min with a low speed before being coated. The obtained admixture was coated using a coating device, air-dried, and slitted with a desired size. The slitted samples were maturated for three to seven days. After the maturation was completed, the samples were cut with a desired size, thus yielding films. Tensile strength (TS) and elongation (E) of the films were measured according to the same method as in

Example 1. As a result, the films were found to have a tensile strength of 18.027 Mpa and an elongation of 6.598%.

COMPARATIVE EXAMPLE 2

0.160 g of Avicel was added to 69.309 g of water in a container at room temperature, and homogeneously mixed for 20 min. 0.533 g of sucrose fatty acid ester S-1670 was added to the above solution and mixed for 20 min. Subsequently, 1.333 g of sorbitol, 1.333 g of glycerin and 0.267 g of propylene glycol were added to the solution, and heated to 80°C. When the temperature reached 80°C, the heating was stopped, 21.326 g of alginate (manucol LB) and 0.320 g of carageenan, 0.213 g of LBG and 0.160 g of xanthan gum were added to the resulting solution, followed by mixing for one hour. After mixing was completed, the temperature was lowered to 50°C, and 0.107 g of citric acid, 0.160 g of malic acid, 0.042 g of sucralose, 0.042 g of acesulfame-K, 0.084 g of aspartame, 1.280 g of menthol, 0.533 g of herb cotton flavor, 1.173 g of peppermint oil, 1.066 g of citrus oil, 0.533 g of spearmint powder, 0.016 g of methylsalicylate and 0.011 g of a pigment were sequentially added to the above-obtained solution. After mixing was completed, the resulting solution was filtered, transferred to a storage tank and defoamed overnight, and agitated for 30 min with a low speed before being coated. The obtained admixture was coated using a coating device,

air-dried, and slitted with a desired size. The slitted samples were maturated for three to seven days. After the maturation was completed, the samples were cut with a desired size, thus yielding films. Tensile strength (TS) and elongation (E) of the films were measured according to the same method as in Example 1. As a result, the films were found to have a tensile strength of 25.642 Mpa and an elongation of 2.549%.

COMPARATIVE EXAMPLE 3

1.054 g of Avicel was added to 71.487 g of water in a container at room temperature, and homogeneously mixed for 20 min. 0.248 g of sucrose fatty acid ester S-1670 was added to the above solution and mixed for 20 min. Subsequently, 1.162 g of sorbitol, 1.162 g of glycerin and 0.858 g of propylene glycol were added to the solution, and heated to 80°C. When the temperature reached 80°C, the heating was stopped, 12.391 g of alginate (manucol LB), 0.087 g of carageenan, 0.087 g of LBG and 0.087 g of xanthan gum were added to the resulting solution, followed by mixing for one hour. Then, 6.196 g of HP-starch dissolved in cool water was added to the above-obtained solution, followed by mixing for one hour. After mixing was completed, the temperature was lowered to 50°C, and 0.176 g of citric acid, 0.217 g of malic acid, 0.477 g of sucralose, 1.239 g of menthol, 0.477 g of herb cotton flavor,

1.144 g of peppermint oil, 0.953 g of citrus oil, 0.477 g of spearmint powder, 0.014 g of methylsalicylate and 0.010 g of a pigment were sequentially added to the above-obtained solution. After mixing was completed, the resulting solution was filtered, transferred to a storage tank and defoamed overnight, and agitated for 30 min with a low speed before being coated. The obtained admixture was coated using a coating device, air-dried, and slitted with a desired size. The slitted samples were maturated for three to seven days. After the maturation was completed, the samples were cut with a desired size, thus yielding films. Tensile strength (TS) and elongation (E) of the films were measured according to the same method as in Example 1. As a result, the films were found to have a tensile strength of 15.890 Mpa and an elongation of 4.941%.

COMPARATIVE EXAMPLE 4

1.218 g of Avicel was added to 71.560 g of water in a container at room temperature, and homogeneously mixed for 20 min. 0.506 g of sucrose fatty acid ester S-1670 was added to the above solution and mixed for 20 min. Subsequently, 0.157 g of sorbitol, 0.354 g of glycerin and 1.982 g of propylene glycol were added to the solution, and heated to 80°C. When the temperature reached 80°C, the heating was stopped, 8.807 g of alginate (manucol LB), 0.100 g of carageenan, 0.100 g of

LBG, 0.100 g of xanthan gum and 0.550 g of gellan were added to the resulting solution, followed by mixing for one hour. Then, 8.807 g of HP-starch dissolved in cool water was added to the above-obtained solution, followed by mixing for one hour. After mixing was completed, the temperature was lowered to 50°C, and 0.204 g of citric acid, 0.250 g of malic acid, 1.431 g of sucralose, 0.550 g of menthol, 1.321 g of herb cotton flavor, 1.101 g of peppermint oil, 0.550 g of citrus oil, 0.017 g of spearmint powder, 0.010 g of methylsalicylate and 0.323 g of a pigment were sequentially added to the above-obtained solution. After mixing was completed, the resulting solution was filtered, transferred to a storage tank and defoamed overnight, and agitated for 30 min with a low speed before being coated. The obtained admixture was coated using a coating device, air-dried, and slitted with a desired size. The slitted samples were maturated for three to seven days. After the maturation was completed, the samples were cut with a desired size, thus yielding films. Tensile strength (TS) and elongation (E) of the films were measured according to the same method as in Example 1. As a result, the films were found to have a tensile strength of 12.020 Mpa and an elongation of 3.218%.

The compositions of the films prepared in Example 1 and Comparative Examples 1 to 4 and the measured tensile strength (TS) and elongation (E) values were summarized in

Table 1, below.

TABLE 1

Ingredients (g)	E.1	C.E.1	C.E.2	C.E.3	C.E.4
SE	0.479	0.738	0.533	0.248	0.506
Avicel	0.144	0.221	0.160	1.054	1.218
Sorbitol	1.198	1.844	1.333	1.162	0.157
Citric acid	0.096	0.148	0.107	0.176	0.204
Malic acid	0.144	0.221	0.160	0.217	0.250
Xanthan gum	0.144	0.221	0.160	0.087	0.100
LBG	0.192	0.295	0.213	0.087	0.100
Carageenan	0.288	0.443	0.320	0.087	0.100
Gellan	0.000	0.000	0.000	0.000	0.550
Sucralose	0.479	0.058	0.042	0.477	1.431
Acesulfame-K	0.000	0.058	0.042	0.000	0.000
Aspartame	0.000	0.116	0.084	0.000	0.000
Menthol	1.246	1.770	1.280	1.239	0.550
Herb cotton flavor	0.479	0.738	0.533	0.477	1.321
Peppermint oil	1.150	1.623	1.173	1.144	1.101
Citrus oil	0.959	1.475	1.066	0.953	0.550
Spearmint powder	0.479	0.738	0.533	0.477	0.017
Methylsalicylate	0.014	0.022	0.016	0.014	0.010
Pigment	0.010	0.015	0.011	0.010	0.323
Glycerin	1.198	1.844	1.333	1.162	0.354
Propylene glycol	0.240	0.369	0.267	0.858	1.982
HP-starch	4.793	13.278	0.000	6.196	8.807
Alginate (manucol LB)	14.378	0.000	21.326	12.391	8.807
DW	71.891	73.765	69.309	71.487	71.560
Total	100.001	100.000	100.001	100.003	99.998
TS (Mpa)	28.230	18.027	25.642	15.890	12.020
E (%)	7.767	6.598	2.549	4.941	3.218

As shown in Table 1, the case of using starch and alginate as film-forming substances at a ratio of 1:3 to 1:3.5 (Example 1) displayed excellent tensile strength and elongation, compared to the cases of using starch alone (Comparative Example 1), alginate alone (Comparative Example 2) and both starch and alginate at a different ratio from that in Example 1 (Comparative Examples 3 and 4).

EXAMPLES 2 to 8

Films were manufactured with the compositions listed in Table 2, below, according to the same method as in Example 1. The measured physical properties of the films are given in Table 2.

TABLE 2

Ingredients (g)	E.2	E.3	E.4	E.5	E.6	E.7	E.8
SE	0.481	0.462	0.483	0.458	0.462	0.480	0.462
Avicel	0.144	0.138	0.145	0.138	0.231	0.144	0.138
Sorbitol	1.202	1.385	0.724	1.375	1.387	1.200	1.385
Citric acid	0.096	0.092	0.097	0.092	0.000	0.096	0.092
Malic acid	0.144	0.138	0.145	0.138	0.092	0.144	0.138
Xanthan gum	0.144	0.092	0.145	0.092	0.139	0.144	0.092
LBG	0.192	0.138	0.193	0.138	0.092	0.192	0.138
Carageenan	0.288	0.185	0.000	0.183	0.139	0.288	0.185
Gellan	0.000	0.005	0.386	0.000	0.185	0.000	0.000
Sucralose	0.385	0.369	0.386	0.367	0.370	0.082	0.369
Acesulfame-K	0.000	0.000	0.000	0.000	0.000	0.012	0.000
Aspartame	0.000	0.000	0.000	0.000	0.000	0.432	0.000
Menthol	1.154	1.108	1.159	1.100	1.202	1.152	1.108
Herb cotton flavor	0.481	0.462	0.483	0.458	0.601	0.480	0.462
Peppermint oil	1.057	1.015	1.063	1.008	0.000	1.056	1.015
Cinnamon oil	0.000	0.000	0.000	0.000	1.202	0.000	0.000
Citrus oil	0.961	0.923	0.966	0.917	0.555	0.960	0.923
Spearmint powder	0.481	0.462	0.483	0.458	0.000	0.480	0.462
methylsalicylate	0.014	0.014	0.014	0.014	0.005	0.014	0.014
Pigment	0.010	0.009	0.010	0.009	0.009	0.010	0.009
Glycerin	1.202	1.385	0.724	1.375	1.387	1.200	1.385
Edible oil	0.000	0.000	0.483	0.000	0.000	0.000	0.000
Gelatin	0.000	0.000	0.000	0.688	0.000	0.000	0.000
Propylene glycol	0.240	0.231	0.241	0.229	0.231	0.240	0.231
HP-starch	4.807	5.539	4.830	5.501	5.550	4.800	5.539
Alginate (manucol LB)	14.420	16.616	14.489	16.502	16.649	14.400	16.617
DW	72.098	69.233	72.446	68.760	69.371	71.998	69.236
Total	100.001	100.001	99.999	100.000	99.998	100.004	100.000
TS (Mpa)	31.430	31.130	30.000	28.060	33.190	30.660	28.440
E (%)	6.610	7.195	5.937	7.467	8.057	6.698	8.120

As shown in Table 2, like to the result of Example 1, in which the films prepared using starch and alginate as film-forming substances at a ratio of 1:3 to 1:3.5 had excellent tensile strength and elongation, films manufactured using the compositions of Examples 2 to 8, containing additional various ingredients as well as starch and alginate at the ratio in Example 1, were found to have excellent tensile strength and elongation.

EXAMPLE 9

Films were successfully manufactured with the compositions containing a particular therapeutically active agent, listed in Table 3, below, according to the same method as in Example 1.

EXAMPLE 10

Films were successfully manufactured with the compositions containing 2.60 g of acrivastine as a therapeutically active agent, listed in Table 3, below, according to the same method as in Example 1.

EXAMPLE 11

Films were successfully manufactured with the

compositions containing 3.25 g of loratadine as a therapeutically active agent, listed in Table 3, below, according to the same method as in Example 1.

EXAMPLE 12

Films were successfully manufactured with the compositions containing 2.60 g of anhydrous caffeine as a particular therapeutically active agent, listed in Table 3, below, according to the same method as in Example 1.

EXAMPLE 13

Films were successfully manufactured with the compositions containing 0.65 g of nicotine as a particular therapeutically active agent, listed in Table 3, below, according to the same method as in Example 1.

TABLE 3

Ingredients (g)	E.9	E.10	E.11	E.12	E.13
SE	0.46	0.47	0.46	0.47	0.48
Avicel	0.14	0.14	0.14	0.14	0.14
Sorbitol	1.14	1.17	1.16	1.17	1.19
Citric acid	0.09	0.09	0.09	0.09	0.10
Malic acid	0.14	0.14	0.14	0.14	0.14
Xanthan gum	0.14	0.14	0.14	0.14	0.14
LBG	0.18	0.19	0.19	0.19	0.19
Carageenan	0.27	0.28	0.28	0.28	0.29
Sucralose	0.10	0.11	0.11	0.11	0.11
Acesulfame-K	0.07	0.07	0.07	0.07	0.07
Aspartame	0.19	0.20	0.20	0.20	0.20
Menthol	1.09	1.12	1.12	1.12	1.15
Mint powder	0.46	0.47	0.46	0.47	0.48

Peppermint	1.00	1.03	1.02	1.03	1.05
Citrus spice mint	0.91	0.94	0.93	0.94	0.95
Spearmint powder	0.46	0.47	0.46	0.47	0.48
Methylsalicylate	0.01	0.01	0.01	0.01	0.01
Pigment	0.01	0.01	0.01	0.01	0.01
Glycerin	1.14	1.17	1.16	1.17	1.19
Propylene glycol	0.23	0.23	0.23	0.23	0.24
Anhydrous caffeine	5.20	0.00	0.00	2.60	0.00
Acrivastine	0.00	2.60	0.00	0.00	0.00
Loratadine	0.00	0.00	3.25	0.00	0.00
Nicotine	0.00	0.00	0.00	0.00	0.65
HP-starch	4.56	4.68	4.65	4.68	4.77
Alginate (manucol LB)	13.67	14.04	13.95	14.04	14.32
DW	68.34	70.22	69.75	70.22	71.62

Industrial Applicability

As described hereinbefore, the present composition that is characterized by containing starch and alginate at a ratio of 1:2.5 to 1:4 offers excellent tensile strength and elongation to films prepared using the same, and allows the films to contain a large amount of antimicrobial/flavoring agents. Therefore, the present composition makes it possible to manufacture films effective in oral cleaning and delivery of additional medicients.

Claims

1. An orally consumable film composition comprising a mixture of starch and alginate at a ratio of 1:2.5 to 1:4.

2. The orally consumable film composition according to claim 1, wherein the ratio of the starch to the alginate is 1:3 to 1:3.5.

3. The orally consumable film composition according to claim 1, further comprising an antimicrobial agent, a flavoring agent or mixtures thereof.

4. The orally consumable film composition according to claim 3, the antimicrobial agent is selected from the group consisting of menthol, methylsalicylate, eucalyptol, thymol and peppermint.

5. The orally consumable film composition according to claim 1, further comprising a filler.

6. The orally consumable film composition according to claim 5, wherein the filler is selected from the group consisting of microcrystalline cellulose, cellulose polymers, magnesium carbonate, calcium carbonate, ground limestone, silicates, clay, talc, titanium dioxide, calcium

phosphate and mixtures thereof.

7. The orally consumable film composition according to claim 1, further comprising a plasticizing agent.

8. The orally consumable film composition according to claim 7, wherein the plasticizing agent is selected from the group consisting of polyols, polycarboxylic acids, polyesters, glycerols and glycols.

9. The orally consumable film composition according to claim 1, further comprising a stabilizing agent.

10. The orally consumable film composition according to claim 9, wherein the stabilizing agent is selected from the group consisting of carageenan, locust bean gum (LBG), xanthan gum and mixtures thereof.

11. The orally consumable film composition according to claim 1, further comprising a saliva secretion-stimulating agent.

12. The orally consumable film composition according to claim 11, wherein the saliva secretion-stimulating agent is selected from the group consisting of citric acid, lactic acid, malic acid, succinic acid, ascorbic acid, adipic acid,

fumaric acid and tartaric acid.

13. The orally consumable film composition according to claim 1, further comprising a sweetening agent.

14. The orally consumable film composition according to claim 13, wherein the sweetening agent is selected from the group consisting of sucralose, acesulfame and aspartame.

15. The orally consumable film composition according to claim 1, further comprising a therapeutically active agent.

16. The orally consumable film composition according to claim 15, wherein the therapeutically active agent is selected from the group consisting of chlorpheniramine maleate, brompheniramine maleate, dexchlorpheniramine, triprolidine hydrochloride, acrivastine, azatadine maleate, loratidine, phenylephrine hydrochloride, dextromethorphan hydrochloride, ketoprofen, sumatriptan succinate, zolmitriptan, loperamide, famotidine, nicotine, caffeine, diphenhydramine hydrochloride, and pseudoephedrine hydrochloride.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2004/000218

A. CLASSIFICATION OF SUBJECT MATTER

IPC7 A61K 9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
KOREAN PATENTS AND APPLICATIONS FOR INVENTIONS SINCE 1975

Electronic data base consulted during the intertnational search (name of data base and, where practicable, search terms used)
CAPLUS(STN), WPI, USPATFULL, JAPIO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 2002300853 A (ASAHI DENKA KOGYO KK) 15 OCTOBER 2002 see the whole document	1-16
A	WU, Y. et al., 'Moisture loss and lipid oxidation for precooked ground-beef patties packaged in edible starch-alginate-based composite films' Journal of Food Science, 2001, Vol.66(3), P.486-93 see the whole document	1
A	CN 1181889 A (MAO CHUNSHENG) 20 MAY 1998 see the whole document	1
A	WO 96/02638 A1 (CIBA-GEIGY AG) 1 FEBRUARY 1996 see the whole document	1

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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